MAY - 3 2000

K000438

510(k) SUMMARY

(As Required by 21 CFR 807.92)

Date Prepared: February 8, 2000

Submitter Name: BioSurgical Corporation
Contact:
Terry E. Laas
President
5990 Stoneridge Drive, Suite 112
Pleasanton, CA 94588
Phone: (925) 734-3009 Fax: (925) 737-1859

Device Name: BioSurgical Multi Lumen Suction Syringe Spray Dispenser
Common/Usual/Classification Name: Piston Syringe
Devices to which Substantial Equivalence is claimed: Hemaedics Duoflo Dispenser and the BioSurgical Sealouette™ Droplet Applicator

Description of the Device:

Allows two common syringes to dispense two different solutions through a common mixing Dispenser prior to application. It can also be attached to standard hospital wall suction for removal of debris, excess tissue or foreign particles in the surgical wound.

The BioSurgical Multi Lumen Suction Syringe Spray Dispenser (modified device) consists of the identical main housing, dual chamber syringe barrel, common plunger, and mixing chamber. The mixed solution is applied directly from the application lumen of the modified device onto a stream of USP medical gas to spread the surgical solution onto the tissue surface.

The modified device is substantially equivalent to the predicate devices.

Intended Use:

Allows two common syringes to dispense two different solutions through a common mixing Dispenser prior to application. It can also be attached to standard hospital wall suction for removal of debris, excess tissue or foreign particles in the surgical wound.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2000

Mr. Terry Laas
President
BioSurgical Corporation
5990 Stoneridge Avenue, Suite 112
Pleasanton, California 94588

Re: K000438
Trade Name: Multi Lumen Suction Syringe Spray Dispenser System
Regulatory Class: II
Product Code: FMF
Dated: February 8, 2000
Received: February 10, 2000

Dear Mr. Laas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K000438

Device Name: Multi Lumen Suction Syringe Spray Dispenser

Indications For Use

Allows two common syringes to dispense two different solutions through a common mixing Dispenser prior to application. It can also be attached to standard hospital wall suction for removal of debris, excess tissue or foreign particles in the surgical wound.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use __
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000438